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RESEARCH ARTICLE

Efficacy of a telephone-based intervention among patients with type-2 diabetes; a randomized controlled trial in pharmacy practice

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Abstract

Background Pharmacists' interventions to improve outcomes of diabetes management have been promising. However, evidence on using telephone-based interventions in pharmacy practice are limited, particularly in developing countries. *Objective* To evaluate the efficacy of a telephone-based intervention to improve care and clinical outcomes in type-2 diabetes. *Setting* A referral community pharmacy and drug information center. *Method* We conducted a two-armed randomized controlled trial on 100 patients with type-2 diabetes. The intervention consisted of 16 telephone calls in 3 month by a trained pharmacist working in an academic drug information center, while the control group received usual care. Before random allocation, patients attended a live education session delivered by pharmacists to learn the basics of diabetes care and to confirm the eligibility criteria. Assessments were performed at baseline, month-3 (after intervention), and month-9 (follow-up). *Main outcome measure* Hemoglobin A1c (HbA1c). *Results* Eighty four patient completed the trial. Baseline variables were comparable between the two groups and the baseline value of hemoglobin A1c was 8.00 ± 1.44 in the study population. HbA1c was significantly improved in both groups at month-3 (6.97 ± 1.41 vs. 7.09 ± 1.78) and remained steady at month-9 (6.96 ± 1.44 vs. 7.26 ± 1.85). Lipid profile showed small improvements in the intervention group but was not significant. The adherence score and self-care score improvement was significantly higher in the intervention group at month-3 and were maintained at month-9. *Conclusion* Medication adherence and self-care significantly improved in the telephone-based intervention group. However, the improvement of clinical outcomes might have been diluted due to the live diabetes education session.

Keywords Diabetes education · Diabetes Type-2 · HbA1c · Iran · Medication adherence · Pharmacist · Self-care · Telephone counseling

Impacts on practice

- Telephone-based intervention by a pharmacist may not enhance the effect of live education to improve HbA1c among patients with type-2 diabetes if delivered consecutively.
- Medication adherence and self-care may improve through a telephone-based intervention by a pharmacist in 3 and 9 months follow up.
- Drug information centers can be proactive in providing patient education to resolve drug therapy problems including medication adherence.

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Introduction

Diabetes is a chronic medical condition with considerable morbidity and mortality worldwide. According to the International Diabetes Federation, the global prevalence of diabetes among adults (aged 20–79 years) is estimated to be 8.8% in 2015 and approximately 75% of patients with diabetes reside in developing countries [1]. The prevalence of type-2 diabetes is projected to be 10.4% in 2040 which is associated with an aging population, sedentary lifestyles, and obesity [1, 2]. Despite new diabetes management approaches to individualize therapeutic goals, studies still report a Hemoglobin A1c (HbA1c) goal of < 7.0% or < 53 mmol/mol as a quality of care indicator and is consistently reported to be below 55% of the on-treatment type-2 diabetes patients [3, 4]. Inadequate adherence to treatment plans including medication therapy and lifestyle modifications has been recognized as underlying factors [3, 5, 6]. Therefore, novel strategies and models of care are essential to improve the diabetes care particularly in developing countries to account for their specific barriers of access to diabetes care [7, 8].

Community pharmacists are often the most accessible health care providers who can play a beneficial role in diabetes care [9]. Pharmacists have successfully provided medication therapy management, consultation on diabetes self-care, blood glucose self-monitoring, adherence to therapy, and routine eye/foot examination [10–14]. Systematic reviews of interventional studies on the role of pharmacists in urban pharmacies, hospitals, and clinics have shown improvements in clinical outcomes of patients with diabetes particularly reduction of HbA1c [9, 15]. However, the models of pharmacist care for patients with diabetes has not been entirely evaluated in developing countries [16].

In recent years, considerable attention has been placed on tele-pharmacy services [17, 18]. The use of telecommunication tools such as telephone, email, short messages, and video call has brought notable achievements in improving service delivery and reducing costs [19, 20]. A number of studies have shown benefits of phone interventions for improving diabetes management [21, 22]. Few studies have evaluated the effect of telephone consultations by pharmacists on the outcomes of diabetes care particularly in developing countries [23–25].

Aim of the study

In the present study, we evaluated the effect of a pharmacist's telephone-based intervention to improve medication adherence, self-care activity, and HbA1c in short- and mid-term follow-ups (3 and 9 months) in patients with type-2 diabetes using oral hypoglycemic medications.

Ethics approval

The study was approved by the research ethics committee of Tehran University of Medical Sciences (ID: 91-03-156-19496).

Methods and materials

Trial design

This study was a parallel-group randomized controlled trial with 1:1 allocation ratio. We planned to assess the effect of a telephone-based intervention by a trained pharmacist for patients with type-2 diabetes (Trial ID: IRCT201212108612N1). All patients attended a one-day live diabetes education session before recruitment. A written consent was obtained from study participants. The CONSORT checklist for reporting of clinical trials is provided as Appendix 1 [26].

Study setting

We carried out the diabetes education sessions and the intervention using the facilities of a referral pharmacy affiliated with the College of Pharmacy, Tehran University of Medical Sciences (conference hall and the drug information call center). This pharmacy is in the midtown area of Tehran, the capital city of Iran, and is the main pharmacy among 7 educational pharmacies affiliated with the College. These pharmacies provide general and specialty medications and dispense over 3500 prescriptions per day [27, 28].

For the diabetes education session, a pharmacist certified as a diabetes educator provided training on the basics of diabetes disease, elements of diabetes management, self-care (diet, exercise, blood sugar monitoring, foot examination, smoking), drug therapy (particularly oral medications and their possible side effects), and hands-on training for blood glucose self-monitoring devices. The training session was designed based on similar programs provided by a nationally recognized diabetes education foundation (GABRIC; http://www.gabric.ir/history). Expert opinions were sought from the diabetes educator pharmacist, clinical pharmacists, and the study consultant endocrinologist [14]. This one-day diabetes education session was held for groups of 10–15 patients. They received a self-monitoring blood glucose device with a supply of test strips required for 3 months. A logbook for documenting the blood glucose levels was also provided.

Eligibility criteria and recruitment

Inclusion criteria were: a diagnosis of type 2 diabetes, use of oral hypoglycemic medications, and a HbA1c greater than 7% within the preceding month. Moreover, patients' ability to use a blood glucose self-monitoring device was confirmed before recruitment. Exclusion criteria were: patients who received adjunct insulin therapy, patients with concurrent heart failure (stage IV), patients who fasted on Ramadan month, and patients who had received diabetes education within the previous 6 months.

Patients were screened for recruitment into the study using two methods. First, a poster advertising the project was displayed in 7 community pharmacies affiliated with the College of Pharmacy, Tehran University of Medical Sciences. Patients contacted the study coordinating center for initial assessment. Second, medical charts of patients in a private diabetes clinic were screened by the staff and eligible patients were referred to the study coordinating center to participate in the project.

Randomization and blinding

We used a balanced block randomization method to generate random allocation sequence. Due to the nature of the study intervention, blinding of participants and caregivers was not performed. One of the authors who was not involved in eligibility confirmation, diabetes education, or telephone intervention generated and concealed the allocation sequence. After the live education session, the clinical team asked for study group allocation via phone.

Intervention

The intervention consisted of 16 phone calls for consultation by a trained pharmacist working in the drug information call center. The phone calls were conducted during a 3-month period. Patients received two calls per week for the first month and one call per week for the second and third month of the intervention. A pre-defined checklist was prepared for the pharmacist to guide each telephone follow up. The pharmacist reinforced the trainings provided in the live session, discussed the trend of blood glucose levels, and solved drug therapy problems or referred the patients to their physician when appropriate.

Study outcomes

The primary outcome of the study was HbA1c. The secondary outcomes were changes in lipid profile (LDL, HDL, triglyceride, and total cholesterol), patient's medication adherence measured by Morisky Medication Adherence questionnaire (8 items) [29], and self-care practice assessed by Self-Care Activities Measure [30] questionnaire. For the clinical data, all patients were referred to a specific laboratory accredited by the Ministry of Health. HbA1c was measured using a chromatography method certified by NGSP to give DCCT compatible results (DS5 A1C Analyzer, Drew Scientific Inc, Dallas, TX). The questionnaires were translated and validated using protocols suggested by the developer's guide or the guideline proposed by International Society of Pharmacoeconomics and Outcomes Research [31].

Patients' demographics and clinical data were obtained from patients and their weight/height was measured at the live education session. The study outcomes were measured at 3 time point: before the intervention (baseline = month 0), after the intervention (month-3), and at follow-up (month-9). The medication adherence and self-care activities questionnaires were completed by phone interview. Patients were reminded by phone to complete laboratory testing.

Sample size

The study sample size was calculated based on an effect size of 0.7% reduction in HbA1c [25]. A significance level of 0.05 and study power of 90% was assumed. The calculated sample size was 88. However, a sample of 106 patients was assumed to be sufficient to compensate for a 15% attrition rate.

Data analysis

Data was entered in the statistical software and quality checks were performed for possible data entry errors. Demographic and baseline clinical data was summarized as frequency or mean ± SD. Independent *t* test or Chi squared test was used to compare values between study groups. Analyses of the primary outcome (HbA1c) and secondary outcomes (lipid profiles and the medication adherence score) was carried out using repeated measure ANOVA. For the self-care activity measure, the Mann–Whitney U Test was employed as the variable was not continuous and normally distributed. Medication adherence levels (low, medium, high) were compared using Chi squared test (linear-by-linear association). To analyze changes between each time point, we used paired *t* test for HbA1c or Wilcoxon test for categorical outcomes.

Results

The study was conducted from June 2013 to January 2015. We initially evaluated 152 patients and recruited 100 eligible participants after confirming inclusion criteria. The flow diagram of the trial is illustrated in Fig. 1. Fifty patients were randomized to the intervention group and 50 patients to the control group. The demographic characteristics were

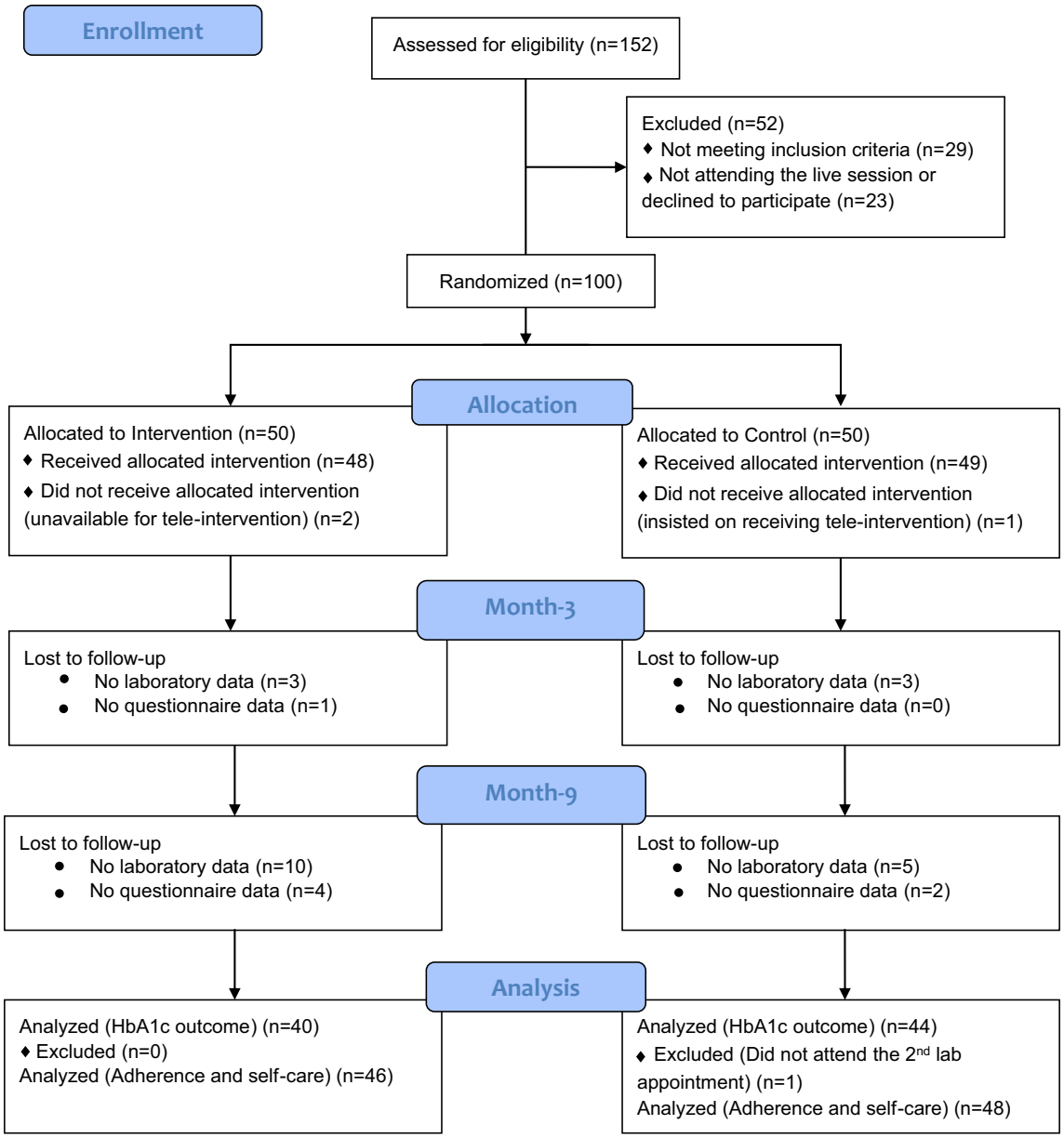

Fig. 1 Flow diagram of study recruitment and analysis. (One patient insisted on receiving the telephone-based intervention and was dropped out because of being randomly allocated to the control group.)

similar between groups (Table 1). Moreover, there were no significant differences between groups regarding the duration of diabetes, number or type of diabetes medications, and the baseline HbA1c.

Regarding the primary outcome, repeated measure ANOVA analysis showed no significant difference in HbA1c level over the study period between study groups (no significant interaction term; sphericity assumption violated, Greenhouse–Geisser correction: $F = 0.29$, $p = 0.78$). A significant effect of time was detected while considering the whole study population which shows an overall improvement of HbA1c during the study ($F = 21.93$, $p < 0.001$, Partial $Eta^2 = 0.21$). No significant difference was detected in within-subjects contrasts analysis between level 1 versus level 2 and level 2 versus level 3 between groups ($p = 0.46$ and 0.60, respectively). The HbA1c was improved in both groups during the first 3 months and was maintained until the month-9 follow-up as illustrated in Fig. 2. In the intervention group, the amount of HbA1c reduction was 0.81 ± 1.12 between baseline and month-3 and 0.01 ± 1.30 between month-3 and month-9. However, the corresponding values in the control group were 1.03 ± 1.41 and -0.17 ± 1.70, respectively.

Table 1 -Baseline characteristics of the study participants

Parameters	Intervention (n = 50)	Control (n = 50)	*p* value
Male gender	28 (54.9)	31 (62.0)	0.54
Age (mean ± SD)	53.4 ± 10.3	56.7 ± 11.5	0.13
Body Weight (mean ± SD)	80.3 ± 16.8	79.7 ± 18.4	0.86
Body Mass Index (mean ± SD)	29.2 ± 4.8	29.9 ± 5.2	0.45
No education on diabetes	41 (82.0)	34 (68.0)	0.11
Duration of diabetes (years)	7.0 ± 8.1	6.2 ± 6.0	0.59
Baseline HbA1c	7.9 ± 1.2	8.0 ± 1.6	0.62
Education			0.56
High school or lower levels	36 (72)	31 (62)	
College graduate	1 (2)	4 (8)	
Bachelor's degree	8 (16)	8 (16)	
Master's degree	3 (6)	5 (10)	
Doctorate or above	2 (4)	1 (2)	
Diabetes medications (mean ± SD)	2.0 ± 0.8	1.9 ± 0.8	0.62
Metformin	47 (94)	49 (98)	0.31
Glyburide	26 (52)	29 (58)	0.55
Pioglitazone	8 (16)	5 (10)	0.37
Repaglinide	6 (12)	5 (10)	0.75
Acarbose	4 (8)	4 (8)	1.00
Gliclazide	4 (8)	3 (6)	1.00
No change in pharmacotherapy during the study	96.0%	97.9%	0.99

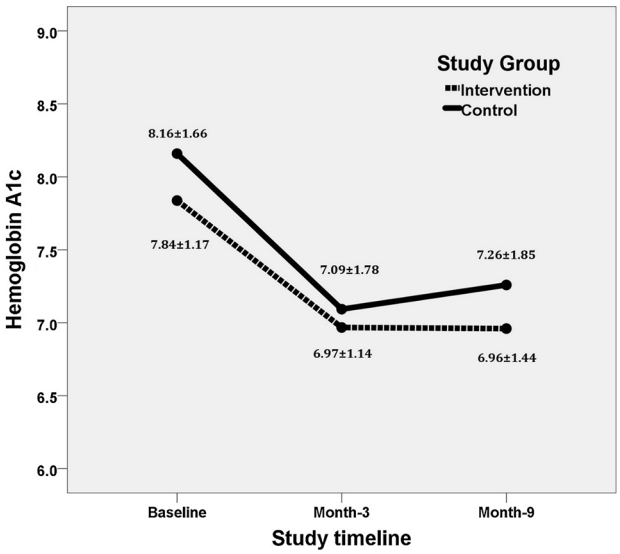

Fig. 2 The trend of hemoglobin A1c during the study. Values at each time point are reported as mean ± standard deviation. No significant difference was observed between groups (sphericity not assumed; Greenhouse–Geisser correction: F = 0.29, $p = 0.78$). An overall improvement of HbA1c in the study population was detected (F = 21.93, $p < 0.001$, Partial Eta2 = 0.21)

Considering the lipid profile (TC, HDL, LDL, TG) values, no significant interaction was detected between study groups and time which shows a similar overall pattern during the study (all p values > 0.3). There was a significant time effect for LDL and HDL during the study ($p < 0.05$ and $p < 0.01$). In the analysis of contrasts, the significant time effect was shown to be from month-3 to month-9 ($p < 0.01$). The details of lipid profile results are summarized in Table 2.

For the self-care activity measures, between group analysis showed that general and specific diet scores were significantly higher at month-3 and month-9 in the intervention group (all p values < 0.05). In addition, the exercise score was significantly higher at month-9 follow-up in this group ($p < 0.05$). Within group comparisons revealed that all self-care measures were improved in the intervention group at month-3. At month-9, the improvements increased for general diet and blood glucose self-monitoring and were maintained for other measures. For the control group, the general diet was improved during the study. The foot care score was increased at month-3 and blood glucose self-monitoring was improved at month-9. Smoking habits were not significantly different at baseline (20% vs. 12% reported smoking) or at follow-ups (Table 3).

Low medication adherence was approximately 45% among the study population and was similar between groups at baseline. In the intervention group, the improvement in adherence score was significantly higher during the trial as

Table 2 Comparison of lipid profile changes between study groups

Variable	Baseline		Month-3		Month-9		*p* value
	Intervention	Control	Intervention	Control	Intervention	Control	
TC (mg/dl)	171.2 ± 41.1	159.0 ± 42.2	168.0 ± 37.2	163.7 ± 40.8	162.9 ± 35.5	158.2 ± 49.6	0.63
LDL (mg/dl)	94.7 ± 31.1	87.0 ± 29.4	91.3 ± 29.4	88.7 ± 33.1	82.4 ± 30.8	83.8 ± 37.8	0.37
TG (mg/dl)	159.8 ± 74.6	156.3 ± 59.9	172.5 ± 103.9	153.2 ± 62.8	164.1 ± 85.9	160.9 ± 67.2	0.39
HDL (mg/dl)	41.5 ± 8.8	44.5 ± 12.0	42.2 ± 8.9	42.6 ± 11.4	45.7 ± 12	46.3 ± 10.8	0.35

Values are reported as mean ± standard deviation

p values are for group × time interaction. Analysis was performed with 40 patients in the intervention group and 44 patients in the control group with all three data points available

Table 3 Comparison of self-care activity measures between two study groups

Self-care domain	Baseline		Month-3		Month-9	
	Intervention	Control	Intervention	Control	Intervention	Control
General diet	0.0 (0.0)	0.0 (0.0)	6.5 (2.0)**	4.0 (6.0)**	6.0 (4.0)**	3.0 (6.0)**
Specific diet	2.5 (1.7)	2.7 (1.5)	3.5 (1.5)*	3.0 (1.6)*	3.7 (2.5)**	2.7 (1.5)**
Exercise	1.0 (3.5)	1.5 (3.0)	3.5 (2.0)	2.0 (3.1)	3.5 (3.0)*	2.0 (3.0)*
Blood glucose Self-monitoring	1.0 (2.7)	1.0 (3.2)	3.0 (1.7)	3.0 (2.0)	3.0 (2.0)	3.0 (2.0)
Foot care	3.5 (7.0)	3.5 (5.5)	7.0 (0.0)	7.0 (2.7)	7.0 (0.0)	7.0 (2.5)
Smoking	10 (20.0%)	6 (12.0%)	4 (8.2%)	6 (12.0%)	8 (17.4%)	5 (10.4%)

General diet, specific diet, exercise, blood glucose self-monitoring, and foot care values are reported as Median (interquartile range). Each domain has two questions and each question asks "the number of days of the previous week" which the patient has followed recommendations of self-care

Smoking is reported as number of active smokers in each study group

Mann–Whitney U Test: **p* value < 0.05; ***p* value < 0.01

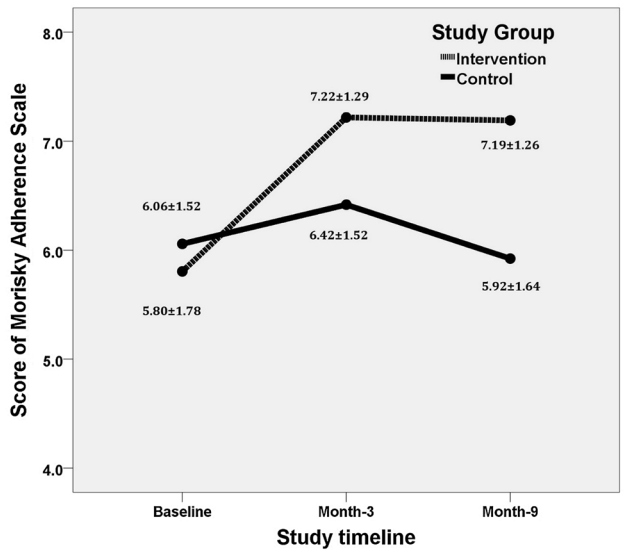

Fig. 3 The trend of medication adherence score during the study. Values at each time point are reported as mean ± standard deviation. Repeated measure ANOVA shows a significant interaction effect of time and study group which infers the higher effect of intervention (F = 10.18, $p < 0.01$, Partial Eta2 = 0.1). In pairwise comparison, adherence score is improved in both groups from baseline to month-3

shown in Fig. 3 (sphericity assumed; F = 10.18, $p < 0.01$, Partial $Eta^2 = 0.1$). In pairwise comparison within groups, adherence score was improved in both intervention and control group from baseline to month-3 ($p < 0.01$ and = 0.03 respectively). Comparison of level 1 versus level 2 in the analysis of contrasts between groups was statistically significant ($p < 0.01$) while level 2 versus level 3 was similar. The adherence score was categorized according to the scale guide and the results are summarized in Table 4. Analysis showed that medication adherence level was significantly higher in the intervention group at both follow-ups. Low adherence at month-9 was 17.4% in the intervention group while it was 52.1% in the control group.

Discussion

The study results showed more improvement in medication adherence and self-care activities in the intervention group. However, both intervention and control group experienced similar reductions in HbA1c at month-3 which was continued up to month-9. The patients' lipid profile changes were also comparable between groups during the study period.

Table 4 -Comparison of adherence level between two groups

Adherence	Baseline		Month-3*		Month-9*	
	Intervention	Control	Intervention	Control	Intervention	Control
Low (< 6)	23 (46.0%)	22 (44.0%)	7 (14.3%)	18 (36.0%)	8 (17.4%)	25 (52.1%)
Medium (6 to < 8)	19 (38.0%)	18 (38.0%)	15 (30.6%)	15 (30.0%)	9 (19.6%)	12 (25.0%)
High (= 8)	8 (16.0%)	9 (18.0%)	27 (55.1%)	17 (34.0%)	29 (63.0%)	11 (22.9%)

p value of Chi squared (linear-by-linear association): * < 0.01

In the present study, we included a one-day live education session for two main reasons. First, most of the study patients were pharmacy customers who did not have an established connection with the research team. Therefore, face-to-face initial assessment was necessary to validate patients' clinical status. Second, patients were not previously trained on the basics of the diabetes self-care and live education was essential to pave the path for the telephone follow-up consultations [25]. At month-3, no difference was observed between intervention and control group. This indicates that the telephone follow-up intervention which was delivered immediately after a one-day education session could not enhance the clinical outcome at short-term follow-up. At the mid-term follow-up (month-9), the difference between groups was not still significant but there was a small increase in HbA1c level in the control group from month-3 to month-9. This observation is interesting and reveals the necessity of a long-term follow-up study to investigate the long-term effects of intervention. Our finding is comparable to the results of two systematic reviews which showed telephone follow-ups may not have significant effect on clinical outcome compared to usual care, however, the review could not find primary studies either conducted in developing countries or in pharmacy practice [25, 32]. Based on the trend of HbA1c observed during the trial, we suggest future studies should include a long term follow-up (e.g. 18 months) to investigate difference between study groups.

We cannot confidently attribute the improvement of HbA1c in both study groups to the live session plus self-monitoring supplies due to lack of a usual care control group. However, our diverse study population was receiving their usual care through different physicians and health plans and it seems unlikely that a major parallel intervention has occurred during the study period. The positive effects of pharmacists' interventions in community pharmacies to improve diabetes care has been evaluated in numerous studies [13, 15, 33, 34]. It would be interesting to confirm if a one-day live education session plus self-monitoring supplies in pharmacy setting could have such a significant impact on diabetes outcomes for patients with an average HbA1c level of 8.00% specifically in developing countries [16].

Management of dyslipidemia in patients with diabetes is an essential element and guidelines recommend lifestyle modification and statin therapy based on patients' cardiovascular risk factors [35, 36]. Although we observed improvements in general and specific diet for the intervention group, no significant difference was observed between groups in lipid profile values. Nevertheless, a consistent trend of increase in HDL level and decrease in LDL, TG, and TC was seen in the intervention group. We should reiterate that the present study was not powered to detect difference in lipid profile and the post hoc power analysis confirmed this lack of power for lipid outcomes. Regarding the main effect of time for the lipid profile measures, we observed a significant change in LDL and HDL which was only detected between second and third time points. As no significant change was detected during the first 3 months, an inference of causal effect related to the live education session should be made with caution.

Patients' adherence to medications was significantly improved in both groups at month-3 and the improvement was larger in the intervention group. As the changes in pharmacotherapy were minimal during the follow up period, we hypothesize that improvement in HbA1c outcome at month-3 is probably mediated through increase in adherence and self-care [37]. Adherence and self-care improvements were maintained through month-9 in the intervention group although this did not translate into improved glycemic control for this time point. This finding should be interpreted considering the HbA1c level at month-3 which had reached to approximately 7%. Studies have shown the marginal effect of quality improvement strategies to improve diabetes are higher for patient with poorly controlled diabetes (HbA1c > 8) [38, 39].

Limitations

The study population were self-motivated and were aware of the educational nature of the project. Therefore, they were probably ready to adapt their lifestyle and adherence to diabetes treatment. Although the randomization process in trial design ensures the internal validity of main study comparison, the study findings could be generalized to similar patient populations. Regarding the HbA1c decrease in the first 3 month of the study, we did not have a usual care control group to ensure the effect of the live education. However, the average years from diagnosis was approximately 7 years and most patients did not have pharmacotherapy

changes over the study period to bias this finding. Future studies are required to confirm the capacity of such interventions in pharmacy practice. Due to recruitment of pharmacy customers, clinical records were not available to the research team and patient self-report and their self-archived medical documents were evaluated before the live education session to validate clinical status. Nevertheless, we did not enroll patients with insufficient documentation to assess the eligibility criteria. Supply of self-monitoring of blood glucose free of charge ensured patients access and use during the study which may have influenced the improvement of self-care practice. In a real-world setting, access and use of this product might be limited to patients with health plan coverage or ability to pay out of pocket. Sustainability of non-dispensing roles of pharmacists in the health care system is a major limitation for implementing such innovative services. However, successful models of medication therapy management call centers have become sustainable through performance-based payment and quality ranking of health insurance plans in the U.S. [40]. The risk of contamination between intervention and control group could not be fully ruled out as we did not document patients' social ties to other participants in the study. However, the risk of contamination must be low because the study participants were mostly recruited by advertisement in the community pharmacies.

Conclusions

In conclusion, the present study showed that medication adherence and self-care outcomes can be improved using a telephone-based intervention in short- and mid-term follow-up periods. The effect of such interventions on clinical outcome might not become evident if delivered immediately after live education session within this follow-up time frame. Future studies should evaluate long term effects of telephone-based interventions and test different designs of delivering such interventions in multi-faceted models of diabetes education and care.

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Conflicts of interests We have no conflicts of financial interest to declare. The study was conducted by a team of community pharmacists and clinical pharmacists.

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